

CLAIMS

1. Use of a recombinant HIV-1 Env protein, in which the V3 loop is partially or completely deleted, for preparing a vaccine composition which is capable of inducing an immunity which is at the same time humoral, cellular and mucosal with respect to HIV-1.
2. Use of a protein according to Claim 1, characterized in that it is selected from the group consisting of the recombinant gp160 and gp120 Env proteins in which the V3 loop is partially deleted and the recombinant gp160 and gp120 Env proteins in which the V3 loop is completely deleted.
3. Vaccine composition, characterized in that it comprises:
- a recombinant Env protein according to either Claim 1 or Claim 2,
  - optionally at least one compound selected from the group consisting of:
    - (1) the vaccination adjuvants selected from the group consisting of derivatives comprising divalent or trivalent ions: aluminium hydroxide or calcium phosphate, and muramylpeptide derivatives and
    - (2) liposomes and
  - optionally at least one pharmaceutically acceptable vehicle.
4. Composition according to Claim 3, characterized in that it comprises a recombinant Env protein according to either Claim 1 or Claim 2 which is anchored onto unilamellar synthetic lipid vesicles or which comprise a phosphatidylcholine:cholesterol molar ratio of about 8:1, and which have a size of between 70 and 150 nm, preferably 90 nm.
5. Composition according to either Claim 3 or Claim 4, characterized in that it can advantageously be administered generally or locally.
6. A pharmaceutical formulation intended for oral administration, characterized in that it essentially consists of:

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- a core consisting of a vaccine composition according to ~~either Claim 3 or Claim 4~~<sup>5</sup> embedded in a gelatin and

- a coating selected from the group consisting of a film-forming polymer which is soluble or expandable in water and soluble in solvents and which is selected from the group consisting of cellulose derivatives, polyvinylpyrrolidone, acrylic and methacrylic esters, polyethylene glycols, polyvinyl alcohols, vinylpyrrolidone/vinyl acetate copolymer, vinylpyrrolidone/polyvinyl alcohol copolymer and protein substances such as zein or gliadin.

7. ~~The formulation~~<sup>The formulation</sup> ~~Formulation~~ according to Claim 6, ~~wherein~~<sup>wherein</sup> ~~in that~~ said film-forming agent is selected from the group consisting of cellulose ethers and esters, such as cellulose acetate, cellulose acetate phthalate, cellulose butyrate, ethylcellulose and methylcellulose.

8. ~~The formulation~~<sup>The formulation</sup> ~~Formulation~~ according to Claim 6, ~~wherein~~<sup>wherein</sup> ~~in that~~ said film-forming polymer is combined with at least one plasticizer chosen from glycerol and esters thereof, high molecular weight polyethyleneglycols, ricin oil and citric, phthalic, adipic and sebacic acid esters.

9. ~~The formulation according to Claim 6, wherein~~<sup>The formulation according to Claim 6, wherein</sup> ~~Formulation~~ according to any one of Claims 6 to 8, ~~characterized in that~~ the vaccine composition consists of a freeze-dried mixture of immunosomes onto which a gp120/160 protein is anchored and of trehalose.

10. ~~The formulation according to Claim 6 comprising~~<sup>The formulation according to Claim 6 comprising</sup> ~~Formulation~~ according to any one of Claims 6 to 9, characterized in that it comprises

- a core consisting of a freeze-dried mixture of immunosomes, onto which a gp120/160 protein is anchored, with trehalose, embedded in gelatin and

- a coating consisting of a cellulose derivative, preferably cellulose acetate phthalate.

11. ~~Pharmaceutical~~<sup>Pharmaceutical</sup> formulation intended for local administration to a mucous membrane, ~~characterized in that it essentially consists of a vaccine composition according to either Claim 3 or Claim 4 embedded in glycerol or a glycerol/glycerine-based mixture.~~<sup>consisting essentially of Claim 15</sup>

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The formulation - 24 - 23

12. ~~Formulation~~ according to Claim 11,  
~~characterized in that~~ <sup>wherein</sup> said vaccine composition consists  
of a freeze-dried mixture of immunosomes, onto which a  
gp120/160 protein is anchored, with trehalose.

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